IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ELMER HEISNER, individually and on behalf of JAYNE HEISNER,	)	
Plaintiff,	)	**No. 08-C-593**
v.	)	**HONORABLE DAVID H. COAR**
GENZYME CORPORATION, a Massachusetts corporation,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Elmer Heisner ("Plaintiff" or "Heisner") brought this action against Defendant Genzyme Corporation ("Genzyme" or "Defendant") for violations of state law surrounding the death of his wife, Jayne Heisner ("Decedent"). Now before this Court is Defendant's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) (Docket No. 8). For the reasons stated below, Defendant's motion is GRANTED.

1. FACTS[1]

As an initial matter, Defendant requests that this Court take judicial notice of the fact that "Seprafilm is a Class III device approved through the PMA [premarket approval] process." (Def.'s Reply at 2-4.) The Complaint references Seprafilm's approval by the FDA on December 20, 2000, but does not make clear what approval process or category was applied to the device.

[1]These facts are derived from Plaintiffs' complaint and, for the purposes of this motion, are assumed to be true. *See Davis Companies v. Emerald Casino, Inc.*, 268 F.3d 477, 479 (7th Cir. 2001).

It is certainly possible to "take judicial notice of matters of public record without converting the 12(b)(6) motion into a motion for summary judgment." *Anderson v. Simon*, 217 F.3d 472, 474-75 (7th Cir. 2000) (citing *Henson v. CSC Credit Servs.*, 29 F.3d 280, 284 (7th Cir. 1994)). However, this can be done only where "an undisputed fact in the public record establishes that the plaintiff cannot satisfy the 12(b)(6) standard." *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1081 (7th Cir. 1997).

Plaintiff argues against taking judicial notice of facts surrounding the FDA's approval, stating that "disputable findings exist concerning the Defendant's compliance with the FDA's Medical Device Amendments (MDA) and Premarket approval process in the manufacturing of their product, Seprafilm." (Pl.'s Resp. at 3.) However, this does not contradict the putative fact in question, which is only that the FDA approved Seprafilm as a Class III device pursuant to the PMA process. Whether that process was properly followed by the FDA, or whether Defendant fulfilled its obligations over the course of that process, are disputed issues that cannot be resolved at this early stage. However, neither of these questions contradict the clear, undisputed, and publicly available fact put forward by Defendant; that the FDA approved Seprafilm as a Class III device. As a matter of law, this approval is granted only upon completion of the PMA process. *See* 21 U.S.C. § 360c(a)(1)(C). Therefore, this Court takes judicial notice of the fact that "Seprafilm is a Class III device approved by the FDA pursuant to the PMA process," and leaves open any additional questions regarding the adequacy of that process as applied in this case.

Plaintiff's wife underwent surgery to remove an ovarian cyst on January 19, 2006. A Seprafilm adhesion barrier manufactured and sold by the Defendant was inserted into her body

to prevent post-surgical adhesions from forming between her internal organs and tissue. Plaintiff alleges that Jayne Heisner died on February 22, 2006 as a proximate result of the insertion of Seprafilm into her body. (Compl. ¶ 2.)

Plaintiff's Complaint contains seven counts, generally alleging that Genzyme was negligent in the design, manufacture, and labeling of Seprafilm and that Seprafilm was not fit for its intended use. Defendant has moved to dismiss all seven counts of the Complaint. In his Response to the Defendant's Motion to Dismiss, Plaintiff has asked this Court to dismiss without prejudice Count II, which claimed a failure to disclose under Massachusetts General Law Ch. 93A § 2(a). (Pl.'s Resp. to Def.'s Mot. to Dismiss 14-15.) Dismissal of Count II is GRANTED without prejudice. The remaining counts are:

I. Breach of Implied Warranty of Merchantability under Massachusetts General Law § 2-314.

III. Strict Liability under Illinois tort law, as product was unreasonably dangerous for normal use.

IV. Negligence under Illinois tort law in testing, inspection, design, manufacture, warning, and/or labeling.

V. Negligence *per se* under Illinois tort law due to adulteration and/or misbranding in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, the Sherman Food, Drug and Cosmetic Law, and "other applicable laws, statutes, and regulations," including standards for care and labeling set by 21 C.F.R. §§ 201.56 and 201.57.

VI. Breach of Express Warranty under Illinois tort law

VII. Breach of Implied Warranty under Illinois tort law

2. STANDARD OF REVIEW FOR MOTION TO DISMISS

When considering a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), courts take the allegations in the complaint as true, drawing all possible inferences in favor of the plaintiff. *Killingsworth v. HSBC Bank Nevada, N.A.*, 507 F.3d 614, 618 (7th Cir. 2007).

To state a claim under federal pleading standards, a plaintiff need only provide a "short and plain statement of the claim showing that the pleader is entitled to relief," sufficient to provide the defendant with "fair notice" of the claim and its basis. Fed. R. Civ. P. 8(a)(2); *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1964 (2007). In *Twombly*, however, the Supreme Court seemingly raised the level of factual development required to state a claim, requiring a complaint to contain more than "labels and conclusions," *id.* at 1964-65, and "enough facts to state a claim to relief that is plausible on its face," *id.* at 1974.

The Seventh Circuit has emphasized that *Twombly* "did not … supplant the basic notice pleading standard." *Tamayo v. Blagojevich*, No. 07-2975, 2008 WL 2168638, at *8 (7th Cir. May 27, 2008). The essential requirement of a complaint remains, that it "give the defendant sufficient notice to enable him to begin to investigate and prepare a defense." *Id.* But after *Twombly*, the Seventh Circuit has also recognized that "the factual detail in a complaint may be so sketchy that the complaint does not provide the type of notice of the claim to which the defendant is entitled under Rule 8." *Airborne Beepers & Video, Inc. v. AT&T Mobility, L.L.C.*, 499 F.3d 663, 667 (7th Cir. 2007); *Killingsworth*, 507 F.3d at 619.

3. ANALYSIS

Defendant has filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) that advances several arguments for judgment as a matter of law, including: (1) federal preemption of state law claims pursuant to §360k (seeking dismissal of all counts); (2) failure to state a claim for negligence per se (Count V); (3) failure to identify an express warranty (Count VI); (4) lack of duty to warn (all counts); (5) improper use of conclusions rather than facts (all counts); and (6) terminal failure to satisfy requirements of the Illinois Wrongful Death Act (multiple counts).

a. Preemption

i. Law of the FDCA

The primary issue now before this Court is whether any of Plaintiff's claims are preempted under the Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act (FDCA). 21 U.S.C. § 360c *et seq.* The MDA established a regulatory structure pursuant to which the Food and Drug Administration (FDA) regulates medical devices. Under the MDA, devices are categorized into three classes, based on the level of risk that they pose. Devices used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" are classified as Class III devices. *Id.* § 360c(a)(1)(C). A Class III device is required to undergo a premarket approval (PMA) process "to provide reasonable assurance of its safety and effectiveness" before being marketed. *Id.* During the PMA process, manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA thoroughly reviews. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The FDA must approve the product's design, testing, intended use,

manufacturing methods, performance standards, and labeling. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997). The device in question in this case, Seprafilm, received PMA as a Class III device on December 20, 2000. (*See* Compl. ¶ 12; discussion *supra* p. 1.)

The MDA contains a preemption clause meant to displace state regulations that conflict with requirements imposed by the FDA. The clause states that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to this device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The initial interpretive questions raised by the preemption clause involve the meaning of the word "requirement": (1) whether the federal process or action constitutes a "requirement" imposed by the FDA; and (2) whether state statutes and state tort law impose different and additional "requirements" on manufacturers. If the FDA and state statutory and tort duties both constitute "requirements," then § 360k may dictate that the state requirements be preempted by those imposed by the FDA. *Lohr*, 518 U.S. at 477. If the state requirement creates obligations that are "different from, or in addition to" the relevant federal requirements, then § 360k necessitates preemption. *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 488 (7th Cir. 2005). However, tension between FDA requirements and those created by state law is avoided where the state requirements parallel the federal ones. *Riegel*, 128 S.Ct. at 1011 (declining to address, in the first instance, whether plaintiffs' claims were "parallel" to federal requirements); *Lohr*, 518 U.S. at 496-497 (holding that state requirements that are "substantially identical to" those imposed by the MDA are not preempted).

The Supreme Court recently applied the preemption analysis to the PMA process in *Riegel v. Medtronic*, holding that the specific approval of a device's design and implementation amounts to the imposition of federal requirements, and that both state statutes and state tort duties may be requirements within the meaning of § 360k(a). 128 S.Ct. 999, 1007-8 (2008). *Riegel* involved a number of New York statutory and tort law claims brought against the manufacturer of a balloon catheter that had received PMA. Given the potentially conflicting requirements of the state laws and the PMA process, the Court held that the latter preempted the plaintiff's claims of implied warranty of merchantability, strict liability, and negligence. *Id.* at 1008-9.

ii. Party positions

Defendant argues that all six of the remaining counts of the Complaint are preempted pursuant to § 360k(a). (Def.'s Dismiss Mem. at 4-7.) In response, Plaintiff attempts to find loopholes in the holding of *Riegel.* (*See* Pl.'s Resp. to Def.'s Mot. to Dismiss 4-8.) Plaintiff first notes that manufacturers are required to inform the FDA, under 21 U.S.C. § 360(i), of any new clinical studies or of incidents of death or serious injury related to medical devices that have received PMA. (*Id.* at 5-6.) Plaintiff seems to suggest that, because Genzyme may have failed to meet these reporting requirements, this Court should not accept Genzyme's contention that Seprafilm is an approved Class III device that has met the requirements of the MDA.

Plaintiff also contends that his claims "parallel" the PMA requirements and Good Manufacturing Practice requirements that specify regulations in regard to the manufacturing, design, packaging, labeling, marketing and distribution of medical devices. 21 U.S.C. §§ 360(e,

j, contract); 21 C.F.R. § 820.1. Therefore, Plaintiff argues, his claims should not be preempted for imposing different or additional requirements. (Pl.'s Resp. to Def.'s Mot. to Dismiss 6-8.)

iii. Discussion

Defendant overstates the holding of *Riegel* in arguing that it settles all questions of preemption in this case. It is true that Plaintiff's claims in this case are similar to those that were found, in *Riegel,* to constitute different and additional requirements. The plaintiffs in *Riegel* alleged that a balloon catheter "was designed, labeled, and manufactured in a manner that violated New York common law." 128 S.Ct. at 1001. They made claims of strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter. *Id.* In the instant case, Plaintiff similarly alleges that Seprafilm was negligently designed, manufactured, and labeled. (Compl. ¶¶ 20, 34, 39.) Like the plaintiffs in *Riegel*, he makes claims of strict liability, breach of implied warranty, and negligence. (*Id.* ¶¶ 20, 34, 39.) However, the *Riegel* court expressly declined to address the question of whether the claims were sufficiently "parallel" as to avoid preemption, because the plaintiff had failed to raise this issue before the court of appeals or in their petition for certiorari. 128 S.Ct. at 1011. In addition, *Riegel* does not delve into the compatibility of FDCA preemption and state law claims based on the post-approval reporting requirements of 21 U.S.C. § 360i.

Here, there is at least some possibility that Seprafilm's failure might be attributed to Defendant's negligence in a way that does not conflict with the FDA's requirements. *See, e.g., Mitchell,* 126 F.3d at 907 ("[T]o the extent that the Mitchells' claims for mislabeling, misbranding and adulteration alleged that Collagen had not followed the FDA requirements, the claims were not preempted because, in permitting a cause of action for non-conformity with

federal requirements, state law did not impose a requirement 'different from, or in addition to,' the federal requirements.") (summarizing a previous ruling); *Riegel*, 128 S.Ct. at 1001. As Defendant acknowledges, to the extent that Plaintiff's allegations are concerned not with the nature of Seprafilm as approved by the FDA, but rather with Defendant's action or inaction in its efforts to take part in the PMA process or implement its results, he may be able to satisfy the parallel exception to preemption. (*See* Def.'s Reply at 5 ("An exception [to preemption] is when claims are premised on violations of the federal requirements embodied in the PMA process specific to the challenged device.") (citing *Riegel*, 128 S.Ct. at 1011).)

Whatever merit there may be to Plaintiff's argument regarding parallel requirements, however, the Complaint cannot be saved as it is now formulated. This Court cannot possibly determine whether Plaintiff's claims are based on requirements that are "substantially identical" to those of the FDA without a more precise statement of his claims. *See Lohr*, 518 U.S. at 496-497. As currently pled, each and every count brought by Plaintiff relies either directly or indirectly on the existence of a "defect" in Seprafilm. (*See* Compl. ¶¶ 19-20, 34, 39, 46, 50, 55.) However, if the referenced defect was in fact intrinsic to the product as approved in the PMA, then it is likely if not certain that any finding of liability based on that defect would place additional and/or different burdens on Defendant's product, necessitating preemption pursuant to *Lohr* and § 360k. *See McMullen*, 421 F.3d at 489 (finding that state and federal requirements are not equivalent if a manufacturer could be held liable under state law while complying with federal requirements). Out of practical necessity and the cold calculus of nationwide regulation, the FDA may be aware of a certain failure rate associated with a medical product and yet approve it. A single instance of such failure, while tragic, does not necessarily amount to a

"defect" for purposes of establishing liability that survives preemption. *See Mitchell*, 126 F.3d at 913-15 (upholding summary judgment against plaintiff due to the fact that any judgment premised on product failure which nonetheless complied with the PMA "would necessarily conflict with the determination of the FDA that its requirements rendered the product safe and effective").

Similarly, it may be premature to conclude that Plaintiff cannot succeed in establishing Defendant's liability by means of the reporting requirements created by the FDCA. Though not entirely clear, Plaintiff seems to suggest that some portion of his claims should survive on a distinct basis by way of these requirements. Plaintiff is correct that after receiving PMA, Class III devices are subject to annual reporting requirements. 21 U.S.C. § 360i. These "post-approval reports" must identify all changes made to the device, 21 C.F.R. § 814.84(b)(1), and summarize unpublished data from any clinical investigations or laboratory studies or reports in scientific literature involving the device "that reasonably should be known to the applicant," *id.* § 814.84(b)(2)(i-ii). A manufacturer must also report to the FDA any problems in labeling, malfunctions of devices, and incidents in which a device may have caused death or serious injury. *Id.* § 803.50. At this stage it cannot be said that any liability for failing to meet these requirements is precluded. Nonetheless, Plaintiff's vague suggestion that Defendant violated these reporting requirements does not help Plaintiff avoid dismissal of his claims; Plaintiff has not alleged anything in his Complaint that would put Defendant on notice that the basis of Plaintiff's claim was Genzyme's failure to meet the FDA's reporting requirements. *See* Fed. R. Civ. P. 8(a)(2); *Twombly*, 127 S.Ct. at 1964.

The burden is on Defendant to show "a conflict between the state and federal regulations of the medical devices which threatens to interfere with a specific federal interest." *Mitchell*, 126 F.3d at 913 (quoting *Hernandez v. Coopervision, Inc.*, 691 So.2d 641 (Fla.Dist.Ct.App. 1997)). However, Defendant cannot adequately argue this defense where the Complaint fails to provide the proper level of specificity in its claims. *Brokaw v. Mercer County*, 235 F.3d 1000, 1014 (7th Cir. 2000) ("while the federal rules of notice pleading do not require the plaintiff to allege all of the relevant facts, '[f]or fair notice to be given, a complaint must at least include the operative facts upon which a plaintiff bases his claim.'") (quoted cite omitted). To the extent that Plaintiff may eventually succeed in a claim that rests outside those that are preempted by § 360k, it is unclear from the Complaint as it now stands how such a claim would appear. It is not the responsibility of this Court to restructure Plaintiff's suit so that it alleges claims with some potential for success under the FDCA. *See James Cape & Sons Co. v. PCC Const. Co.*, 453 F.3d 396 (7th Cir. 2006) ("District judges are not mind readers, and should not be required to explain to parties whether or how their complaints could be drafted to survive a motion to dismiss."). At this stage, we find only that every aspect of the Complaint in its current form is either preempted pursuant to § 360k, or lacks sufficient clarity to place Defendant on notice of the claims levied against it. Plaintiff has therefore failed to state a claim upon which relief can be granted, and the Complaint must be dismissed in its entirety. Fed. R. Civ. P. 12(b)(6).

Plaintiff has requested the opportunity to amend his complaint in light of some of the issues addressed in the motion to dismiss filings. It is clear that the defense of preemption has highlighted a lack of clarity in the structure of several of Plaintiff's claims that may be redeemable through amendment. At the very least, Plaintiff must provide some allegations

regarding the nature of the alleged Seprafilm defect as it relates to the FDA approval process. In the interest of justice, Plaintiff will therefore be permitted the opportunity to amend those counts of the Complaint whose failings have only been made clear as a result of the defense of preemption. *See* Fed. R. Civ. P. 15. Therefore, Counts I, III, IV, and VII – related to implied warranties, strict liability, or negligence – are DISMISSED. The remaining Counts V and VI suffer from additional failings that warrant additional discussion.

b. Negligence per se Claim

Count V of Plaintiff's Complaint alleges that Defendant has violated a statute establishing a standard of care, making Defendant negligent *per se*. (Compl. ¶¶ 43, 45, 46.) Under Illinois law, the violation of a statute intended to protect human life or property may establish a prima facie case of negligence. *Kalata v. Anheuser-Busch Cos.*, 144 Ill.2d 425, 434 (1991). To prevail on a claim of negligence based on the violation of a statute, a plaintiff must establish that (1) he was a member of the class of persons the statute was designed to protect, (2) his was the type of injury the statute was intended to protect against, and (3) the defendant's violation of the statute was the proximate cause of his injury. *Id.*

Plaintiff alleges that Defendant violated the standards of care for labeling and provision of information set by 21 C.F.R. §§ 201.56 and 201.57 and that Defendant violated §§ 301 and 331 of the FDCA. (Compl. ¶¶ 43-46.) Plaintiff also alleges that he, "as a purchaser and consumer of Seprafilm, is within the class of persons the statutes and regulations . . . are designed to protect and [his] injury is of the type of harm these statutes are designed to prevent." (*Id.* at ¶ 44.) Plaintiff further alleges that his injuries resulted from the violation of the statutes. (*Id.* at ¶ 47.)

In response to the Complaint, Defendant contends that the regulations in 21 C.F.R. §§ 201.56 and 201.57 do not apply to medical devices such as Seprafilm. (Def.'s Memo. in Supp. of Mot. to Dismiss 7.) Defendant is correct that these regulations apply to "human prescription drug and biological products," not medical devices. 21 C.F.R. §§ 201.56; 201.57. The statutory regulations for Class III medical devices are defined in § 360 of the FDCA, as Plaintiff now acknowledges. (Pl.'s Resp. to Def.'s Mot. to Dismiss 10-11.) So far as Plaintiff alleges that Defendant has violated 21 C.F.R. §§ 201.56 and 201.57, Count V of Plaintiff's Complaint must be dismissed for failing to place Defendant on notice of the underlying standard of care, an essential element of a negligence *per se* claim. *See Kalata*, 144 Ill.2d at 434.

Plaintiff argues in his Response that, because he also alleged that Defendant violated §§ 301 *et seq* and 331, he has pleaded the applicable statutory regulations for medical devices. (*Id.* at 9-10.) Plaintiff suggests that he could amend his Complaint to more specifically allege that Defendant violated the regulations for medical device warnings in 21 C.F.R. 801.1 and 801.6 and the requirements for PMA laid out in 21 U.S.C. § 360(e). (*Id.* at 10.) Such amendment may save this count of Plaintiff's Complaint, but must refer specifically to one or more federal requirements to place Defendant on proper notice of the negligence *per se* claim; if Plaintiff merely reiterates FDCA duties within the context of the PMA, its post-approval implementation, or general reporting requirements, the amended Count V will simply duplicate the claims of Count IV, brought on the basis of overall negligence, and will likely be stricken. *See* Fed. R. Civ. P. 12(f) (enabling a court to strike from a pleading any redundant matter). Therefore, Count V is DISMISSED.

c. Breach of Express Warranty

Count VI of Plaintiff's Complaint alleges that Defendant has breached an express warranty made to Plaintiff, on which Plaintiff relied in using Seprafilm. (Compl. ¶¶ 49-50.)

According to Section 2-313 of the UCC, express warranties are created by:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

810 ILCS 5/2-313(1)(a)-(c) (West 2006). An express warranty creates an obligation on the part of the seller to deliver goods that conform to the promise, description, or model offered by the seller. *Mydlach v. DaimlerChrysler Corp.*, 226 Ill.2d 307, 320 (2007). The warranty is breached if the goods do not conform. *Id.* at 321.[1]

Under an express warranty, the language of the warranty itself dictates the obligations of the parties. *Loeffel Steel Prods., Inc. v. Delta Brands, Inc.*, 379 F.Supp.2d 968, 983-84 (N.D. Ill. 2005); *Hasek v. DaimlerChrysler Corp.*, 319 Ill.App.3d 780, 788 (2001). Express warranty claims are not preempted by § 360k, as they arise from representations made by parties as the

[1] Illinois courts have not been consistent in interpreting the "basis of the bargain" language in § 2-313 to require proof that a plaintiff actually relied on the warranty. *Compare Hasek*, 319 Ill.App.3d at 538 ("The burden is on the seller to establish . . . that the affirmations did not become part of the basis of the bargain.), *with Regopoulous v. Waukegan P'ship*, 240 Ill.App.3d 668, 674 (1992) (requiring purchaser to prove he "actually relied on the warranty"). In this case, however, the issue is irrelevant because Plaintiff alleges that he relied on the warranty.

basis of the bargain between them rather than requirements imposed under state law. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 525 (1992). Were a court to hold that, under state law, a defendant had breached an express representation made to a plaintiff, such a holding would not interfere with the operation of the PMA process. *Mitchell*, 126 F.3d at 915.

Defendant contends, however, that Plaintiff's Complaint must be dismissed because it does not contain sufficient factual allegations about the nature of the express warranty to state a claim. (Def.'s Mem. in Supp. of Mot. to Dismiss 8-9.) Defendant is correct that Count VI of Plaintiff's Complaint essentially repeats the elements required to prevail on a claim for breach of express warranty—that a warranty forming part of the basis of the bargain between the parties was breached by the defendant. *See Hasek*, 745 N.E.2d at 634. Plaintiff alleges that "Genzyme expressly warranted to Plaintiff by and through statements made…orally and in publications, package inserts, and other written materials…that Seprafilm was safe, effective, fit and proper for its intended use." (Compl. ¶ 49.) Plaintiff then alleges that he relied on the warranty in using the device and that the warranty was false. (*Id.* at ¶ 50.)

The Seventh Circuit has not addressed what is required to state a claim based on breach of express warranty. Even before *Twombly*, however, some courts required that plaintiffs at least mention the particular promise or description that allegedly gave rise to an express warranty. For example, in *Johnson v. Brown & Williamson Tobacco Corp.*, a complaint was insufficient when it stated only that the defendant extended an express warranty through its "advertising, marketing and other efforts." 122 F.Supp.2d 194, 206 (D. Mass. 2000). Plaintiff has not pointed this Court to any case suggesting that its allegation that Defendant made "statements…orally and in publications" is sufficient to state a claim for breach of express warranty. The single case

Plaintiff's Response cites in defense of Count VI of his Complaint, *Gelormino v. J.C. Penney Co., Inc.*, actually states that "[s]ince J.C. Penney's allegation of a breach of an express warranty is not supported by any facts, such a mere conclusion of law is legally insufficient." No. CV 960067840, 1997 WL 297601, at *3 (Conn. Super. Ct. May 22, 1997). This unpublished case, moreover, is in no way binding on this Court and has only limited persuasive value.

Post-*Twombly*, the federal pleading standard requires more than "a formulaic recitation of the elements of a cause of action." *Twombly*, 127 S.Ct. 1955, 1964 (2007). The Seventh Circuit has indicated that the factual content of a claim may be too "sketchy" to put a defendant on notice. *Killingsworth*, 507 F.3d at 619. In this case, Plaintiff has offered nothing more than a formulaic recitation of the elements required to prevail on a claim and has alleged no facts at all that suggest an express warranty existed. Plaintiff has not specified any particular affirmation, promise, description, or sample that formed part of the basis of his bargain with Defendant. He thus fails to put the Defendant on notice as to the substance of his claim. This seems to be precisely the type of claim that is too indefinite to meet the *Twombly* standard. Count VI of Plaintiff's Complaint is therefore DISMISSED.

CONCLUSION

In any other instance, a claim of a purported defect related to negligence would likely place Defendant on sufficient notice as to survive dismissal. Within the context of § 360k of the FDCA, however, the word "defect" carries much less meaning, as any such "defect" falling within the scope of the PMA essentially carries no weight for purposes of showing liability under state law. Therefore, the ability of Plaintiff to adequately state a claim according to such allegations is limited, and at present it is not clear that any of his claims might survive those limitations.

During the pendency of a decision on the instant motion to dismiss, Plaintiff amended his complaint. (Docket No. 23.) However, Plaintiff's voluntary amendments as reflected in that document are relatively limited, consisting of: the exclusion of the strict liability count already withdrawn voluntarily; expansion of the general negligence claim to include Defendant's design and manufacture of Seprafilm, as well as its failure to adequately and properly warn "Plaintiff's health care provider purchasing Seprafilm"; changes in the negligence *per se* count to shift its statutory basis; and removal of Count VI for breach of implied warranty. (*See generally id.*) Of these, the only significant change impacting this Court's rationale for granting dismissal involves the new basis for Plaintiff's claim of negligence *per se*. However, this claim is still dependent on the purported "defect" that this Court has already found to be lacking in clarity. In the interest of efficiency this Court will not ask the parties to re-argue a motion to dismiss on this one count before Plaintiff has had the opportunity to resolve the failings identified in this opinion. Therefore, the Amended Complaint does not save Plaintiff's claims, and it is similarly dismissed without prejudice.

For the reasons stated above, Defendant's motion to dismiss is GRANTED. Counts I, II, III, IV, V, VI, and VII of the Complaint are DISMISSED WITHOUT PREJUDICE. Plaintiff's Amended Complaint is also DISMISSED WITHOUT PREJUDICE. Plaintiff will be granted leave to amend his Complaint on or before August 18, 2008 in light of this Opinion.

Enter:

/s/ David H. Coar

David H. Coar
United States District Judge

Dated: **July 25, 2008**